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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,573	11/28/2003	Mark William James Ferguson	39-289	4956

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NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
JIANG, DONG	
ART UNIT	**PAPER NUMBER**
1646	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/722,573	FERGUSON, MARK WILLIAM JAMES	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-27,29 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-27,29 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's amendment filed on 11 January 2007 is acknowledged and entered. Following the amendment, claim 28 is canceled, and the new claim 30 is added.

Currently, claims 25-27, 29 and 30 are pending and under consideration.

Withdrawal of Objections and Rejections:

All objections and rejections of claim 28 are moot as the applicant has canceled the claim.

The rejection of claim 27 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment.

Formal Matters:

Specification

Title

The newly amended title of the invention is still not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed (the method).

Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-27 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 is indefinite because it is unclear what "a partially modified form of IFN-γ" refers to, and whether it is sequence or chemical modifications, or something else, and the specification does not clearly define such. The metes and bounds of the claim, therefore, cannot be

determined. Applicants argument filed on 11 January 2007 has been fully considered, but is not deemed persuasive for reasons below.

At page 5 of the response, the applicant argues that a description of what is intended by "partially modified form of IFN-γ" is found on page 5, lines 7-14, and that from a reading of this description, an artisan would appreciate the meets and bounds of the phrase. This argument is not persuasive because the specification merely states that "a partially modified form of IFN-γ *may, for example*, have a longer half-life than IFN-γ, alternatively, it may be an inhibitor of IFN-γ metabolism", and "partially modification *may be* by way of addition, deletion or substitution of amino acid residues". This argument is not persuasive because such language is merely *exemplary*, but is not considered, in itself, to provide definitive limitations for the term. Further, as indicated in the examples, the term seems to encompass, besides the sequence variants of IFN-γ, structurally and functionally diverse molecules, such as "an inhibitor of IFN-γ metabolism". Therefore, without clear limitation for the term, the metes and bounds of the claim, therefore, cannot be determined.

The remaining claims are included in this rejection because it is dependent from the specifically mentioned claims without resolving the indefiniteness issue belonging thereto.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-27 and 29 remain rejected, and the new claim 30 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record set forth in the last Office Action mailed on 11 October 2006, at pages 3-5.

Applicants argument filed on 11 January 2007 has been fully considered, but is not deemed persuasive for reasons below.

At pages 6-7 of the response, the applicant argues that the examiner appears possibly to be confused with regard to the specification's teaching relating to the different proposed uses of inhibitors of IFN-γ and stimulators of IFN-γ, as many of the passages cited by the Examiner relate to the anti-scaring effects of inhibitors of IFN-γ, as opposed to the pro-healing effects of stimulators of IFN-γ; and that anti-IFN-γ treatment is indeed anti-scaring and improves the quality of the dermal architecture, however, in the case of chronic wounds, where healing is already delayed to a deleterious extent, the quality of the scar is of minor clinical importance, and the primary clinical aim is to aid the healing. This argument is not persuasive because the issue is not just the matter of priority, i.e., wound healing is the primary concern in the case of chronic wounds comparing to improving the scar, rather the issue is that it is unclear whether IFN-γ is suitable for the treatment of chronic wounds as the specification does not disclose any working example related to the treatment of chronic wounds and the present invention is entirely based on extrapolation of the results from treating acute wounds, and such is not sufficient to enable the claimed invention because the result of treating *chronic* wound with IFN-γ is not predictable as the art has established that the wound healing is extremely complicated. The most important message from the prior art references cited by the Examiner is not about the anti-scaring effects of inhibitors of IFN-γ, as opposed to the pro-healing effects of stimulators of IFN-γ; rather most important message is that the treatment of chronic wounds cannot be predicted from the treatment of acute wounds as they involve different mechanisms.

At pages 7-8 of the response, the applicant argues that Although it would clearly have been desirable to include data from chronic wounds in the present specification, at the priority date of the invention, no universally accepted animal model of chronic wound healing existed, and that although extrapolation from acute wounds may have been viewed as "less than satisfactory", and although experimentation on the part of an artisan wishing to practice the invention may be necessary, the artisan would have realized it represented the best technique available at the time, and Applicant had minimized the need for such experimentation to the extent possible, and that no undue burden of experimentation exists. This argument is not persuasive because "the best technique available", or lack of existing or accepted animal model of chronic wound healing is not the reason to entitle a patent application to a lower standard of

enablement, and this is about an *inventive* concept, not what was available or existed. Given the nature of the invention, treating chronic wounds, which is extremely complex and unpredictable, and the state of the prior art, which establishes the unpredictability of chronic wound healing (indicating the need for working examples), a working example becomes particularly important. MPEP indicates lack of a working example, however, is a factor to be considered, especially in a case involving an unpredictable and undeveloped art (MPEP 2164.02).

In *In re Fisher*, 427 F. 2d 833, 839, 166 USPQ 18, 24 (CCPA 1970), the court clearly states: "in cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved". In the present case, the specification discloses an example of treating acute wounds with IFN-γ, and claims a method for treating chronic wounds with the same based on extrapolation from the results of treating acute wounds. In the absence of working example of treating chronic wounds, and the presence of the unpredictability directed to same established by the prior art, further experimentation would be required to determine whether IFN-γ is indeed suitable for treating chronic wounds, which, by no means, a *routine* experimentation.

Conclusion:

No claim is allowed.

Advisory Information:

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dong Jiang, Ph.D.
Patent Examiner
AU1646
3/28/07

GARY B. NICKOL, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600